CLAIMS

We Claim:

1. A method of treating erectile dysfunction in a patient suffering from a co-morbid condition comprising the step of:

placing an erection-inducing amount of a semi-solid composition in the *fossa navicularis* of the patient, the semi-solid composition comprising:

a vasoactive prostaglandin;

a penetration enhancer;

a polymeric thickener selected from the group consisting of a polysaccharide gum and a polyacrylic acid polymer;

a lipophilic component selected from the group consisting of an aliphatic C_1 to C_8 alcohol, an aliphatic C_8 to C_{30} ester, and a mixture thereof; and

an acidic buffer system.

2. The method in accordance with claim 1 wherein the vasoactive prostaglandin is selected from the group consisting of PGE_1, PGA_1, PGB_1, $PGF_{1\alpha}$, 19-hydroxy-PGA_1, 19-hydroxy-PGB_1, PGE_2, PGA_2, PGB_2, 19-hydroxy-PGA_2, 19-hydroxy-PGB_2, PGE_3, $PGF_{3\alpha}$ and mixtures thereof.

3. The method in accordance with claim 1 wherein the vasoactive prostaglandin is prostaglandin E_1.

4. The method in accordance with claim 1 wherein the vasoactive prostaglandin is present in the amount of 0.001 weight percent to about 1 weight percent, based on the total weight of the composition.

5. The method in accordance with claim 1 wherein the vasoactive prostaglandin is present in the amount of about 0.07 weight percent to about 0.4 weight percent, based on the total weight of the composition.

6. The method of claim 1 wherein the semi-solid composition is packaged as a unit dose and the vasoactive prostaglandin is present in the amount of about 0.05 mg to about 0.8 mg per unit dose.

7. The method in accordance with claim 1 wherein the polymeric thickener is a polyacrylic acid polymer.

8. The method in accordance with claim 1 wherein the polymeric thickener is a shear-thinning polysaccharide gum.

9. The method in accordance with claim 8 wherein the shear-thinning polysaccharide gum is a galactomannan gum.

10. The method in accordance with claim 8 wherein the shear-thinning polysaccharide gum is a modified galactomannan gum.

11. The method in accordance with claim 10 wherein the modified galactomannan gum is a modified guar gum.

12. The method in accordance with claim 1 wherein the composition has a viscosity of about 5,000 cps to about 20,000 cps.

13. The method in accordance with claim 1 wherein the composition has a viscosity of about 7,000 cps to about 13,000 cps.

14. The method in accordance with claim 1 wherein the penetration enhancer is selected from the group consisting of an alkyl-2-(N-substituted amino)-alkanoate, an alkyl-2-(N,N-disubstituted amino)-alkanoate, an (N-substituted amino)-alkanol alkanoate, an (N, N-disubstituted amino)-alkanol alkanoate, pharmaceutically acceptable salts thereof and mixtures thereof.

15. The method in accordance with claim 1 wherein the penetration enhancer is dodecyl 2-(N, N-dimethylamino)-propionate hydrochloride.

16. The method in accordance with claim 1 wherein the lipophilic component comprises at least one aliphatic C_8 to C_{30} ester.

17. The method in accordance with claim 1 wherein the lipophilic component comprises at least one glyceryl ester selected from the group consisting monoglycerides, diglycerides, triglycerides, and mixtures thereof.

18. The method in accordance with claim 1 wherein the lipophilic component comprises at least one glyceryl ester selected from the group consisting of glyceryl monooleate, triolein, trimyristin, tristearin, and mixtures thereof.

19. The method in accordance with claim 1 wherein the acidic buffer system provides a buffered pH value for said composition in the range of about 3 to about 7.4.

20. The method in accordance with claim 1 wherein the acidic buffer system provides a buffered pH value for said composition in the range of about 3 to about 6.5.

21. The method in accordance with claim 1 wherein the composition further comprises an emulsifier selected from the group consisting of sucrose esters, polyoxyethylene sorbitan esters, long chain alcohols, and glyceryl esters.

22. The method in accordance with claim 1 wherein the emulsifier comprises at least one glyceryl ester selected from the group consisting of glyceryl monooleate, triolein, trimyristin, tristearin, and mixtures thereof.

23. The method in accordance with claim 1 wherein the composition further comprises up to about 5 percent myrtenol, based on the total weight of the composition.

24. The method in accordance with claim 1 wherein the composition further comprises a preservative.

25. The method in accordance with claim 1 wherein the composition further comprises a topical anesthetic.

26. The method in accordance with claim 1 wherein the composition further comprises a fragrance.

27. The method in accordance with claim 1 further comprising administering the composition on demand.

28. The method in accordance with claim 1 further comprising administering the composition about 5 minutes to about 15 minutes before sexual intercourse.

29. The method in accordance with claim 1 further comprising administering the semi-solid prostaglandin E_1 composition at least twice a week.

30. The method in accordance with claim 1 further comprising administering the semi-solid prostaglandin E_1 composition every other day.

31. The method in accordance with claim 1 further comprising administering the semi-solid prostaglandin E_1 composition daily.

32. The method in accordance with claim 3 wherein the composition is packaged as a unit dose and prostaglandin E_1 is present in the amount of about 0.1 mg to about 0.5 mg per unit dose.

33. The method in accordance with claim 3 wherein the composition is packaged as a unit dose and prostaglandin E_1 is present in the amount of about 0.1 mg to about 0.3 mg per unit dose.

34. The method in accordance with claim 3 wherein the composition comprises:

about 0.001 weight percent to about 1 weight percent prostaglandin E_1;

about 0.5 weight percent to about 10 weight percent dodecyl 2-(N,N dimethylamino)-propionate hydrochloride;

about 0.5 weight percent to about 10 weight percent ethyl alcohol;

about 0.5 weight percent to about 10 weight percent ethyl laurate; and

about 0.01 weight percent to about 5 weight percent modified guar gum,

based on the total weight of the composition.

35. A method of treating erectile dysfunction in a patient suffering from the co-morbid condition of diabetes mellitus comprising the step of placing in the *fossa navicularis* of the patient an erection-inducing amount of a semi-solid prostaglandin E_1composition comprising:

a penetration enhancer;

a shear-thinning polymeric thickener selected from the group consisting of a polysaccharide gum and a polyacrylic acid polymer;

a component that is selected from the group consisting of an aliphatic C_1 to C_8 alcohol, an aliphatic C_8 to C_{30} ester, and a mixture thereof; and

an acidic buffer system.

36. A method of treating erectile dysfunction in a patient suffering from the co-morbid condition of hypertension comprising the step of placing in the *fossa navicularis* of the patient an erection-inducing amount of a semi-solid prostaglandin E_1 composition comprising:

a penetration enhancer;

a shear-thinning polymeric thickener selected from the group consisting of a polysaccharide gum and a polyacrylic acid polymer;

a component that is selected from the group consisting of an aliphatic C_1 to C_8 alcohol, an aliphatic C_8 to C_{30} ester, and a mixture thereof; and

an acidic buffer system.

37. A method of treating erectile dysfunction in a patient suffering from the co-morbid condition of cardiac disease comprising the step of placing in the *fossa navicularis* of the patient an erection-inducing amount of a semi-solid prostaglandin E_1 composition comprising:

a penetration enhancer;

a shear-thinning polymeric thickener selected from the group consisting of a polysaccharide gum and a polyacrylic acid polymer;

a component that is selected from the group consisting of an aliphatic C_1 to C_8 alcohol, an aliphatic C_8 to C_{30} ester, and a mixture thereof; and

an acidic buffer system.

38. A method of treating erectile dysfunction in a patient having the co-morbid condition of recovering from prostatectomy comprising the step of placing in the

fossa navicularis of the patient an erection-inducing amount of a semi-solid prostaglandin E_1 composition comprising:

a penetration enhancer;

a shear-thinning polymeric thickener selected from the group consisting of a polysaccharide gum and a polyacrylic acid polymer;

a component that is selected from the group consisting of an aliphatic C_1 to C_8 alcohol, an aliphatic C_8 to C_{30} ester, and a mixture thereof; and

an acidic buffer system.

39. A method of treating a patient suffering from erectile dysfunction unresponsive to oral phosphodiesterase-5 inhibitor therapy comprising the step of placing in the *fossa navicularis* of the patient an erection-inducing amount of a semi-solid prostaglandin E_1 composition comprising:

a penetration enhancer;

a shear-thinning polymeric thickener selected from the group consisting of a polysaccharide gum and a polyacrylic acid polymer;

a component that is selected from the group consisting of an aliphatic C_1 to C_8 alcohol, an aliphatic C_8 to C_{30} ester, and a mixture thereof; and

an acidic buffer system.

40. The use of prostaglandin E_1;

a penetration enhancer selected from the group consisting of an alkyl-2-(N-substituted amino)-alkanoate, an alkyl-2-(N,N-disubstituted amino)-alkanoate, an (N-substituted amino)-alkanol alkanoate, an (N, N-disubstituted amino)-alkanol alkanoate, pharmaceutically acceptable salts thereof and mixtures thereof;

a polymeric thickener selected from the group consisting of a polysaccharide gum and a polyacrylic acid polymer;

a lipophilic component selected from the group consisting of an aliphatic C_1 to C_8 alcohol, an aliphatic C_8 to C_{30} ester, and a mixture thereof; and an acidic

buffer system for the preparation of a pharmaceutical composition for treating erectile dysfunction in a patient suffering from a co-morbid condition including at least one of diabetes mellitus, hypertension, cardiac disease, history of prostatectomy or erectile dysfunction unresponsive to oral phosphodiesterase-5 inhibitor therapy, whereby the pharmaceutical composition is to be placed in the *fossa navicularis* of the patient.